08/882,435

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/882,435	06/25/97	HOXIE	[illegible]

EXAMINER: [illegible]

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ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 11/10/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8-25-98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-2, 4-24 is/are pending in the application.
Of the above, claim(s) 11-24 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-2, 4-10 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-24 have been previously ~~are~~ subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1998-421-6

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges Applicant's Amendment, Paper No. 12, filed August 25, 1998. In view of Applicant's Amendment, the status of the claims is as follows: Claim 3 has been canceled; Claims 11-24 are withdrawn from consideration; Claims 1-2 and 4-10 are currently pending before the Examiner.

Upon review and reconsideration of Applicant's earlier filed provisional applications, Applicant's presently claimed invention has been accorded benefit of the earlier effective filing date of application Serial No. 60/020,396, filed June 25, 1996. Applicant's arguments are deemed persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-2 and 4-10 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is vague and indefinite in the recitation "anti-immunodeficiency virus antibody" since it is unclear whether the antibody is directed to a viral protein or to a chemokine receptor on a cell. Amendment of claim 1 to delete "anti-immunodeficiency virus" would obviate this rejection.

Applicant's arguments have been considered but are not deemed persuasive. Common usage in the antibody art is to set forth the specificity of the antibody, i.e., an "anti-immunodeficiency virus antibody" would be construed by the ordinary artisan as an antibody specific for an immunodeficiency virus, not a cellular receptor. Similarly, an anti-CD4 antibody would be specific for CD4, not immunodeficiency virus. Claim 4 is vague and indefinite in the recitation "HIV receptor protein" since it is unclear whether the antibody is directed to a viral receptor such as gp160 or a cellular receptor such as CD4 which binds to HIV. Amendment of claim 4 to more clearly point out and define what is intended to be encompassed within the metes and bounds of "an HIV receptor" would obviate this rejection. Claim 5 is vague and indefinite in the recitation "cellular cofactor for a cellular HIV receptor" since it is unclear whether the cofactor activity is actually intended to be directed to another cellular receptor such as CD4 or to a cofactor activity for HIV infection. Amendment of claim 5 to more clearly point out and define what is intended to be encompassed by "a cellular cofactor" would obviate this rejection. Claim 8 is vague and indefinite in the recitation "synthetic antibody" since it is unclear what would constitute a "synthetic antibody" since even a monoclonal antibody can be considered a "synthetic antibody". Amendment of claim 8 to more clearly define what is meant by "synthetic" would obviate this rejection. Claims 4-7 are vague and indefinite in the recitation "claim 3" since claim 3 has been canceled. Amendment of claims 4-7 to recite "claim 1" or another claim as appropriate would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most**

nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-9 are directed to **any** "anti-immunodeficiency virus antibody" which can bind to a cellular protein (see claim 1) and, in particular, to a chemokine receptor protein such as CXCR4 or CCR5. However, Applicant specification only sets forth the 12G5 monoclonal antibody which appears specific for the CXCR4 chemokine receptor (fusin) and, as evidenced by Endres et al., *Cell* 87:745-756, 1996 (provided by Applicant), does not bind to other chemokine receptors (see page 748, second column). Further, Applicant's own specification establishes that even with 12G5's specificity for CXCR4, some strains of HIV are able to evade 12G5 inhibition (see page 31, lines 1-15). Further, CXCR4 is the coreceptor of T cell-tropic HIV strains and there is no evidence that 12G5 would inhibit other strains, particularly macrophage-tropic strains (i.e., most primary isolates) which generally utilize CCR5 as a coreceptor with CD4. Further, HIV and SIV appear to utilize a very limited number of coreceptors for infecting cells and Applicant has not set forth evidence of any other antibodies which would bind to **any** cellular protein and inhibit immunodeficiency viruses. Nor has Applicant shown that an "anti-immunodeficiency virus", i.e., an antibody specific for an immunodeficiency virus, would also bind to cellular proteins. As stated above, the art accepted terminology for antibody nomenclature would suggest to one skilled in the art that an "anti-immunodeficiency virus antibody" would specifically bind an immunodeficiency virus antigen. Applicant's specification does not set forth sufficient teachings and guidance to allow one skilled in the art to produce "anti-immunodeficiency virus antibodies" or

anti-chemokine receptor antibodies able to bind **any** cellular protein or even any chemokine receptor with a reasonable expectation of success and without undue experimentation. It is well known in the art that the production of monoclonal antibodies is unpredictable and that there is a low probability of obtaining the same or similar monoclonal antibodies to a particular antigen. This low probability, together with the particular ability of 12G5 to bind to CXCR4 and inhibit HIV binding, would not allow one skilled in the art to produce the monoclonal antibodies of the claimed invention or similar antibodies without undue experimentation. As the claims must be commensurate in scope with the enablement provided by the specification, the claims should be limited to the 12G5 monoclonal antibody.

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The specification lacks sufficient evidence that the claimed biological materials are either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. The specification lacks sufficient evidence of reproducibility or complete deposit information for the 12G5 cell line producing the 12G5 monoclonal antibody. It is not clear that cell lines possessing the properties of 12G5, particularly the ability to bind CXCR4 and inhibit its coreceptor activity in HIV infection, are known and publicly available or can be reproducibly isolated from nature without undue experimentation. It is well known in the art that exact replication of a particular cell line or a cell line producing an antibody having exact chemical identity with the claimed antibody is an unpredictable event. Therefore, absent evidence of reproducibility or a publicly

available deposit, one skilled in the art would not be able to practice the claimed invention without undue experimentation. Accordingly, filing of evidence of the reproducibility of the claimed cell lines and antibodies, or filing of evidence of deposits commensurate in scope with the claims is suggested.

Applicant's attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

However, it is noted that Applicant's referral to the deposits of 12G5, listed on pages 21-22, particular Applicant's assurances set forth at page 22, first paragraph, are a sufficient assurance that all required deposits have been made and all conditions of 37 C.F.R. 1.801-1.809 properly met. Therefore, Applicant's specification is deemed to have satisfied the requirements for deposit set forth in this rejection.

The declaration filed on August 25, 1998, under 37 C.F.R. 1.131 has been considered but is ineffective to overcome the following reference of Feng et al.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Feng et al. reference. The declaration does not specifically state that the work evidenced in the declaration was performed in this country or in a NAFTA or WTO member country. Applicant should note that a new declaration containing the same evidence **and** a statement that the work was performed in the United States or a NAFTA or WTO member country will be favorably considered and deemed to overcome the Feng et al. reference and the rejections set forth below.

Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(a) as anticipated by Feng, et al. (Science, May 1996) for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant's declaration is insufficient for the reasons set forth above. Submission of an appropriate declaration as set forth above would overcome this rejection.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng, et al. (Science, May 1996) for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant's declaration is insufficient for the reasons set forth above. Submission of an appropriate declaration as set forth above would overcome this rejection.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Chris Eisenschenk, can be reached at (703) 308-0452.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at

(703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
November 9, 1998